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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,179	02/15/2002	Pierre Rosenzweig	SANSYL007	1648
27546	7590	03/02/2004	EXAMINER	
SANOFI-SYNTHELABO INC. 9 GREAT VALLEY PARKWAY P.O. BOX 3026 MALVERN, PA 19355			JONES, DWAYNE C	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/069,179	ROSENZWEIG, PIERRE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-4,6,9-11,14-16,18 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4,6,9-11,14-16,18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 2-4, 6, 9-11, 14-16, 18, and 21-23 are pending.
2. Claims 2-4, 6, 9-11, 14-16, 18, and 21-23 are rejected.
3. Claims 1, 5, 7, 8, 12, 13, 17, 19, and 20 are canceled as per the amendment of November 24, 2003.

### ***Response to Arguments***

4. Applicants' arguments filed November 24, 2003 have been fully considered but they are not persuasive. Applicant presents the following arguments. First, applicant argues that Wurtman et al. is directed to the suppression of weight gain usually associated with the cessation of tobacco use, whereas the instant invention is directed to using MAO inhibitors to decrease the body weight of an obese patient. Second, applicant argues that the only eating disorders referred to in Benedetti et al. are anorexia and bulimia, two conditions that are largely irrelevant to obesity.
5. First, applicant argues that Wurtman et al. is directed to the suppression of weight gain usually associated with the cessation of tobacco use. In addition, applicant purports that Wurtman et al. do not teach or suggest the use of MAO inhibitors to decrease the body weight of an obese patient, especially, for example, one, who was not a tobacco user. Wurtman et al. specifically teach that it is well established in the art that the neurotransmitter of serotonin (5-HT) modulates a variety of body systems, glands, neurons. In fact, Wurtman et al. specifically disclose that the serotonergic

neurons are involved with inter alia, appetite, (see column 2, lines 42-53). The methods described in Wurtman et al. are directed to the administration of compounds that are effective in decreasing weight gain and the consumption of high carbohydrate foods, (see column 3, lines 47-57). Wurtman et al. specifically recite that there is a decrease in weight gain and even a lower consumption of high carbohydrate foods by the administration of serotonergic drugs, (see column 4, lines 3-51). This teaching clearly provides one skilled in the art with the motivation to use compounds that are known to have an effect of enhancing serotonin-mediated neurotransmission, which embraces compounds that are serotonin reuptake inhibitors as well inhibitors of monoamine oxidase. Accordingly, the instant claims are obvious in view of these teachings from Wurtman et al. . Consequently, the skilled artisan is provided with the motivation to employ these compositions to treat obesity as instantly claimed.

6. Moreover, the instant claims not only are directed to treating obesity but are open-ended with the word comprising. Applicant recites the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310. For this reason, the instant claims cover additional components and do not rule out that a tobacco smoker could be treated for weight loss, as disclosed in the prior art rejection of Wurtman et al. in view of Benedetti et al.

7. Second, applicant argues that the only eating disorders referred to in Benedetti et al. are anorexia and bulimia, two conditions that are largely irrelevant to obesity.

However the rejection of record is Wurtman in view of Benedetti et al. Because Wurtman et al. teach to the skilled artisan to utilize serotonergic compounds, which includes inhibitors of MAO, for the treatment of weight gain, the prior art reference of Benedetti et al. was used to simply provide additional examples of inhibitors of MAO. It would have been obvious to one having ordinary skill in the art, especially in view of the Wurtman et al., to use other serotonergic compounds, which includes inhibitors of MAO, including those listed in Benedetti et al.

### ***Claim Objections***

8. Claim 23 is objected to as being dependent upon a objected claim 22, see below in paragraph No.
9. In addition, the following is noted in order to advance prosecution that instant claim 23 is dependant on claim 22, which is objected to as being a substantial duplicate of claim 10. It is recommended the claim dependency of claim 23 be changed to another claim, namely claim 10.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The rejection of claims 2-4, 6, 9-11, 14-16, 18, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wurtman et al. of U.S. Patent No. 4,999,382 in view of the Benedetti et al. Wurtman et al. teach of compositions and methods of utilizing serotonergic and anorectic drugs to decrease weight gain as well as lower consumption of high-carbohydrate foods, (see column 3, lines 47-57). Wurtman et al. specifically teach that it is well established in the art that the neurotransmitter of serotonin (5-HT) modulates a variety of body systems, glands, neurons. In fact, Wurtman et al. specifically disclose that the serotonergic neurons are involved with inter alia, appetite, (see column 2, lines 42-53). Wurtman et al. also teach that in lieu of or in addition to, "d-fenfluramine, d,l-fenfluramine and fluoxetine, other drugs which have the effect of enhancing serotonin-mediated neurotransmission can be administered . . .e.g., moclobemide . . .brofaromine", (see column 4, lines 3-6 and lines 34-38).
12. The prior art reference of Benedetti et al. teach provides and lists various inhibitors of MAO, inter alia, tolaxatone, brofaromine, and moclobemide, (see page 98, 1st paragraph and pages 101-103) as well as milacemide, (pages 74-76). In addition, Benedetti et al. teach that inhibitors of MAO are known to be effective in the treatment of eating disorders, (see pages 90 and 91).
13. Since Wurtman et al. teach that compounds of utilizing serotonergic and anorectic drugs to decrease weight gain as well as lower consumption of high-carbohydrate foods, it would have been obvious to one having ordinary skill in the art utilize other compounds that simply possess the pharmacologically property of serotonergic and anorectic drugs, such as tolaxatone, brofaromine, and moclobemide,

and milacemide, etc. The determination of a dosage having the optimum therapeutic index is well within the level of the one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Moreover, it would have been obvious to the skilled artisan to employ the use of various and sundry compounds that possess the pharmacological properties as serotonergic drugs and anorectic drugs decreasing weight gain as well as lower consumption of high-carbohydrate foods, as specifically disclosed by Wurtman et al. Consequently, one having ordinary skill in the art would have been motivated to utilize any compounds that possess the pharmacological properties as serotonergic drugs and anorectic drugs for the treatment of obesity and as well as the decreasing the body weight of an individual. In addition, because Wurtman et al. teach to the skilled artisan to utilize serotonergic compounds, which includes inhibitors of MAO, for the treatment of weight gain, the prior art reference of Benedetti et al. was used to simply provide additional examples of inhibitors of MAO. It would have been obvious to one having ordinary skill in the art, especially in view of the Wurtman et al., to use other serotonergic compounds, which includes inhibitors of MAO, including those listed in Benedetti et al.

#### ***Duplicate Claims***

14. Claims 14, 15, 16, 18, 21, and 22 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 2, 3, 4, 6, 9, and 10, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same

thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Conclusion***

15. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and



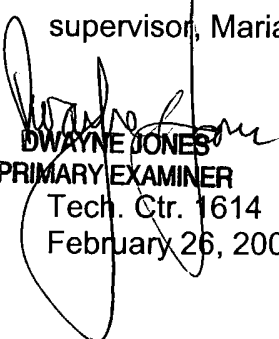
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Fridays from 8:30 am to 6:00 pm. The official fax No. for correspondence is (703) 872-9306.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, may be reached at (571) 272-0584.

  
**DWAYNE JONES**  
**PRIMARY EXAMINER**  
Tech. Ctr. 1614  
February 26, 2004